

traversed.

Swart Fails To Disclose the Claimed *Markush* Group of Carriers or Adjuvants

At the outset, Applicant has previously overcome a 35 U.S.C. §102 rejection of Claims 10, 11 and 14 over Swart. *See* Office Action Response dated 13 January 2009. As Applicant pointed out in the Office Action Response dated 13 January 2009 (p. 7-8), a claim is anticipated only if each and every element is found, either expressly or inherently described, in a single prior art reference. MPEP 2131. Claim 10 is directed to a composition comprising at least one pharmaceutically acceptable carrier or adjuvant selected from the group consisting of fillers, disintegrants, binders, lubricants, stabilizers, flavors, anti-oxidants, preservatives, dispersants, buffers and electrolytes. The pharmaceutically acceptable carrier or adjuvant allegedly present in Swart, namely water, does not fall into any of the recited categories in Claim 10's *Markush* group.

The current Office Action (p. 4) now states for the first time (after Applicant filed a Notice of Appeal and Appeal Brief) that Swart "disclose[s] that the compound was exposed to **nitrogen gas** (Page 74, section entitled 'D. Mass spectrometric analysis'). As evidenced by *Beane*, nitrogen gas is a lubricant." However, section "D. Mass spectrometric analysis" in Swart refers to the set up of the mass spectrometer used. Specifically, clustering of ions with polar solvent molecules during expansion into the vacuum system was prevented by use of a curtain of dry nitrogen gas and nitrogen was also used "as the nebulizing gas for the ionspray LC/MS interface." As previously articulated, Swart appears to be using water as the adjuvant or pharmaceutical carrier – not nitrogen. Accordingly, what Swart describes is not a pharmaceutical formulation comprising 2-N-propylamino-5-hydroxytetralin and nitrogen as the lubricant.

Additionally, the Office Action's reliance on *Beane* in an anticipation rejection is improper. MPEP 2131.01 sets forth three situations in which it is proper to cite an additional reference in making a 35 U.S.C. §102 rejection, *i.e.* to:

- (A) Prove the primary reference contains an "enabled disclosure;"
- (B) Explain the meaning of a term used in the primary reference; or
- (C) Show that a characteristic not disclosed in the reference is inherent.

The Office Action seemingly is using Beane to allegedly prove Swart contains an “enabled disclosure” of using nitrogen as a lubricant in a pharmaceutical formulation. However, reliance on Beane is improper as (1) Beane is date stamped "accessed online May 5, 2011", which is not indicative of knowledge of one of ordinary skill in the art at the time of invention or enablement of Swart as published in 1994 and (2) Beane refers to a completely different field where lubricants are used, namely liquid rocket engines and flight vehicle power equipment. Specifically, the passage cited by the Examiner on pg. 384, second paragraph reports using nitrogen gas as a lubricant on Inconel-X bearings to test load carrying capacity of gas bearings on flight vehicle power equipment. Furthermore, in the section titled “Gas Lubricated Bearings” (which is not a pharmaceutical formulation), Beane states that the approach is to obtain high temperature lubrication by using gas lubricated bearings and that the advantages are achieved due to the high temperature, providing exemplar temperatures of 1500 °F, which is more than 800 °C. *See* Beane, at p.383-384. This is not the typical conditions for a pharmaceutical formulation. Thus, Beane is improperly relied on in the anticipation rejection, as Beane is not in any way indicative of (1) knowledge of one of ordinary skill in pharmaceutical arts, rather at most knowledge in the liquid rocket engine and flight vehicle power industry, (2) use of nitrogen or lubricants in pharmaceuticals, and (3) proof that Swart used nitrogen as a lubricant. For these reasons, Swart fails to anticipate Claim 10.

2. Objection of Claim 12

Claim 12 is objected to “as depending from a rejected base claim.” However, based on Applicant’s response above, Claim 10 is novel and thus, so is dependent Claim 12. Therefore, Applicant respectfully requests reconsideration and withdrawal of the present objection.

3. Conclusion

It is believed that all of the stated grounds of rejection are properly traversed, accommodated or rendered moot herein. Applicant therefore respectfully requests that the Examiner consider and withdraw all presently outstanding rejections. It is believed that a full

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and complete response has been made to the present Action and that the application is in condition for allowance.

Should any issues remain, the Examiner is invited to call the undersigned at the telephone number given below.

Respectfully submitted,

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